Section 15 – 510(k) Summary

#K130684

1. Date Summary Prepared

2. Submitter's Name and Address

Philips Medical Systems
22100 Bothell Everett Highway
Bothell, Washington 98021

OCT 18 2013

3. Contact Person

Nancy Burke
Senior Regulatory Affairs Specialist
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Facsimile: 425-487-7758

4. Device Name and Classification Panel Information

Proprietary Name:	Philips HeartStart Model 861388 (text and graphics only) and Model 861389 (ECG) AEDs
Common Name:	Automated External Defibrillator
Classification Name: (Primary)	Automated External Defibrillator, 21 § 870.5310, Product Code MKJ
Classification Name: (Secondary)	Low energy DC Defibrillator, 21 § 870.5300, Product Code LDD
Device Classification:	Class III pre-amendment (primary) Class II (secondary)

5. Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the Philips Heartstart Automated External Defibrillator (FR3) Models 861388 and 861389 with the optional 3-Lead ECG Cable, optional Rechargeable Clinical Use Battery and optional CPR Meter with Q-CPR Technology are:

- Philips HeartStart models 861388 and 861389 ("FR3"), 510(k) #K111693
- Philips Heartstream FR2+ with ECG Cable, 510(k) #K013425
- Philips Heartstream FR2+ with Rechargeable Battery, 510(k) #K014157
- Laerdal Medical CPRmeter CPR Feedback Device, 510(k) #K122050
- HeartStart MRx monitor/defibrillator with Q-CPR option, 510(k) #K051134

The design of the Philips Heartstart AED (FR3) Models 861388 and 861389 with the optional 3-Lead ECG Cable, optional Rechargeable Clinical Use Battery and optional CPR Meter with Q-CPR Technology is substantially equivalent in safety and performance to the devices listed above.

6. Device Description

These battery powered, automated external defibrillators are available in two models, one with ECG (model 861389) and the other in text only (model 861388). Both models include the Philips SMART biphasic, impedance-compensating exponential waveform and a multi-parameter Patient Analysis System (PAS) algorithm for determining if the rhythm is shockable. The models 861389 and 861388 deliver a nominal 150J to adults and a nominal 50J to infants and children when the optional infant/child key mode is used. As with previous generations of Philips AEDs, the models 861389 and 861388 have several methods of testing themselves and alerting the user if there is a problem. In addition to the periodic self-tests performed each time the device is turned on, both models perform power on self-tests, runtime self-tests, and runtime operation checks. Using voice prompts, text prompts, graphics, audible tones, light emitting diodes (LEDs) and buttons, the responder is guided through the event.

The models 861388 and 861389 are compatible with several accessories. These items including the Smart Pads III, the Infant/Child Key, a non-rechargeable training battery, an optional Bluetooth transceiver module, an optional data card, an optional language card an optional rechargeable Clinical Use Battery, an optional 3-Lead ECG Cable, an optional CPR Meter with Q-CPR Technology, and various carry cases.

7. Intended Use

The models 861388 and 861389 are intended for use by trained responders to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). The models 861388 and 861389 are used with disposable defibrillator pads applied to potential victims of SCA with the following symptoms:

- Unresponsiveness
- Absence of normal breathing

If in doubt, apply the pads.

The models 861388 and 861389 are intended for adults and children over 55 pounds (25 kg) or 8 years old. The models 861388 and 861389 are also intended for children under 55 pounds (25 kg) or 8 years old when used with the optional Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child's age or weight, do not delay treatment. Apply the pads as illustrated for a child and use the defibrillator.

WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings for the CPR feature has not been established in patients under 55 lbs (25 kg) or 8 years old.

The models 861388 and 861389 are intended for use by personnel who have been trained in its operation and qualified by training in basic life support (BLS), advanced life support (ALS) or other physician-authorized emergency medical response.

CPR Meter with Q-CPR® Technology
The models 861388 and 861389 with the optional CPR meter and Q-CPR® Technology are designed for application by a responder trained in its use. It serves as a guide in administering CPR to a suspected sudden cardiac arrest (SCA) victim at least 8 years old or 55 lbs (25 kg). If the age or weight of the patient is in doubt, do not delay treatment. Perform CPR without using the CPR meter.

WARNING: The CPR meter is not intended for use on SCA victims under 8 years old or 55 lbs (25 kg). If the Infant/Child Key is installed in the FR3, the CPR meter is disabled.

When attached to the bare chest of a suspected victim of SCA and connected to a model 861388 or 861389 used with compatible pads properly placed, the CPR meter provides real-time feedback on CPR in accordance with current CPR guidelines. It displays CPR feedback indicators for depth, release, and rate of chest compressions. It also provides notification for lack of expected CPR activity and a stay-clear icon display during FR3 rhythm analysis and shock delivery. In addition, the FR3 prompts the responder when it detects hyperventilation of the patient.

3-Lead ECG Cable
At the discretion of a responder trained in its use, the 3-Lead ECG Cable can be connected to the model 861389 to provide a non-diagnostic ECG display of the patient's heart rhythm. The responder can select to display lead vectors I, II, or III.

The system is intended for use on a conscious or breathing patient, regardless of age, for attended patient monitoring. While connected to the 3-Lead Cable, the defibrillator's shock capability is disabled, but the model 861389 continues to evaluate the patient's ECG.

8. Comparison of Technology Characteristics

The waveform used in the models 861389 and 861388 are unchanged in terms of specifications, nominal energy and peak current from those described in the previous submission, 510(k) #K111693. The algorithm used to determine shock recommendations and the SMART CPR algorithm that supports the CPR First function are also unchanged. Optional accessories offered with the models 861389 and 861388 are not changed from the previous submission.

Like the FR2+, the models 861388 and 861389 may be used with an optional Lithium Ion rechargeable battery. The batteries are similar in performance, use and safety characteristics. When used with a rechargeable battery, both the predicate device and the models 861388 and 861389 perform tests for battery status, provide indications of battery status, and provide low battery and replace battery prompts as needed.

Also like the FR2+, the model 861389 may be used with the optional 3-lead ECG cable to monitor ECG function; however, unlike the ECG Cable provided for the FR2+ which contains a battery, the ECG cable for the model 861389 is powered by the model 861389.

The CPR meter with Q-CPR technology is offered as an optional accessory with the models 861388 and 861389 for use during CPR and detects motion and force based on an embedded accelerometer and force sensor. The CPR meter is attached to and powered by the models 861388 and 861389, in the same manner as the Philips Compression Sensor offered with the Philips MRx Monitor/Defibrillator, while the CPRMeter™ by Laerdal is battery-powered. Feedback to the responder for depth, release, rate of compressions are similar between the CPR meter and the predicate devices. Ventilation information detected by attached defibrillator pads is provided by the models 861388 and 861389 and is a subset of that provided on the MRx, while the Laerdal stand-alone CPRMeter™ does not provide any ventilation feedback as it is not used with connected defibrillator pads.

9. Data Used in Determination of Substantial Equivalence

The models 861389 and 861388 employ many of the same technologies as those used in the predicate devices. Testing demonstrates that the models 861389 and 861388 perform in a manner substantially equivalent to the predicates and do not raise any new issues of safety or effectiveness.

10. Conclusion

The introduction of the models 861389 and 861388 with the new accessories and features are within the predicate device functionality and the differences do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 18, 2013

Philips Medical Systems
Nancy Burke
Senior Regulatory Affairs Specialist
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K130684
Trade/Device Name: Philips HeartStart FR3 AED models 861388 (Text) and 861389 (ECG)
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LDD, DPS, LIX
Dated: September 11, 2013
Received: September 12, 2013

Dear Ms. Burke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Owen P. Faris -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 12 - Indications for Use

510(k) Number (if known)

#K130684

Device Name

Philips HeartStart FR3 Automated External Defibrillator (AED), Models 861388 and 861389

Indications for Use

The FR3 is intended for use by trained responders to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). The FR3 is used with disposable defibrillator pads applied to potential victims of SCA with the following symptoms:

- Unresponsiveness
- Absence of normal breathing

If in doubt, apply the pads.

The FR3 is intended for adults and children over 55 lbs (25 kg) or 8 years old. The FR3 is also intended for children under 55 lbs (25 kg) or 8 years old when used with the optional FR3 Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child's age or weight, do not delay treatment. Apply the pads as illustrated for a child and use the defibrillator.

The FR3 is intended for use by responders who have been trained in its operation and qualified by training in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized emergency medical response program. The FR3 can be configured under the guidance of a Medical Director to enable Advanced Use mode and alternative cardiopulmonary resuscitation (CPR) protocols, such as CPR while Armed, CPR First-User, and CPR First-Always.

> WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings for the CPR First feature has not been established in patients under 55 lb (25 kg) or 8 years old.

CPR Meter with Q-CPR

The FR3 can be used with the optional CPR meter with Q-CPR® technology by Laerdal. The system is designed for application by a responder trained in its use. It serves as a guide in administering CPR to a suspected sudden cardiac arrest (SCA) victim at least 8 years old or 55 lb (25 kg). If the age or weight of the patient is in doubt, do not delay treatment. Perform CPR without using the CPR meter.

> WARNING: The CPR meter is not intended for use on SCA victims under 8 years old or 55 lb (25 kg). If the Infant/Child Key is installed in the FR3, the CPR meter is disabled.

When attached to the bare chest of a suspected victim of SCA and connected to an FR3 used with compatible pads properly placed, the CPR meter provides real-time feedback on CPR in accordance with current CPR guidelines. It displays CPR feedback indicators for depth, release, and rate of chest compressions. It also provides notification for lack of expected CPR activity and a stay-clear icon display during FR3 rhythm analysis and shock delivery. In addition, the FR3 alerts the responder when it detects hyperventilation (more than 12 ventilations per minute) of the patient during CPR.

3-Lead ECG Cable

In addition, at the discretion of a responder trained in its use, the optional FR3 3-Lead ECG Cable can be connected to the FR3 ECG model to provide a non-diagnostic ECG display of the heart rhythm of a patient who is responsive and breathing normally but at risk of cardiac distress. The system is intended for use on a conscious or breathing patient, regardless of age, for attended patient monitoring. The responder can select display of lead vectors I, II, or III. While connected to the 3-Lead Cable, the defibrillator's shock capability is disabled, but the FR3 continues to evaluate the patient's ECG. In addition, the FR3 alerts the responder to check the patient if the ECG indicates that the heart rate is less than 30 BPM or if the heart rhythm may benefit from a defibrillation shock. If the patient's rhythm or status changes, the responder can attend to the patient, as appropriate.

FR3 Rechargeable Battery

The FR3 rechargeable battery is intended for use by organizations, such as EMS or fire departments that use the FR3 frequently and want to decrease cost-per-use and reduce environmental waste. The rechargeable battery should only be used by organizations committed to providing the resources required to operate a battery maintenance program. Due to changes in the performance characteristics of rechargeable batteries over time, it is important for the battery maintenance program to monitor how many battery charge/discharge cycles the battery experiences, in order to determine when to retire it from service. The FR3 rechargeable battery is not recommended for infrequent-use

environments such as office buildings, airlines, or public access defibrillation (PAD) programs. It should not be used as the spare or backup battery; instead, the standard primary battery should be used due to its long shelf-life.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)